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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,675	08/22/2003	Peter T. O'Heeron	122182.00021	1017

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EXAMINER	
FIDEI, DAVID	

ART UNIT	PAPER NUMBER
3728	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,675	O'HEERON	
	Examiner	Art Unit	
	David T. Fidei	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9 and 15-18* is/are pending in the application.

4a) Of the above claim(s) *15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 15-17 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: These claims are directed towards a disposable, shield-less obturator rather than kit.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-17 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 18 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (Patent no. 5,118,297) in view of Metcalf et al (Patent no. 5,453,094). Johnson discloses an obturator generally shown as 10 comprising a proximal end 12 where the obturator is grasped, a distal tip 14 and a shaft 18 between the proximal and distal ends. The shaft is formed as a monolithic structure. An orientation indicator is recited in claim 18 as located near the proximal end, which enables a user to determine by touch the relative position of the tip at the distal end. As shown in figures 1 and 2 of Johnson a washer 22 is disclosed as received adjacent the handle or proximal end. This washer has a wider diameter than shaft 18, particularly at the distal end 14,

and manifestly serves as an orientation indicator to extent claimed. Where a user can determine by touch the relative position of the tip at the distal end.

The difference between the claimed subject matter and Johnson resides in a case for enclosing the at least one obturator. Metcalf et al figures 2-9 disclose that it is notoriously well known to place instrument in cases of individual packages. It would have been obvious to one skilled in the art to provide the at least on obturator of Johnson with a case for enclosing the same as taught by Metcalf, in order to provide a package for shipment and handling of the obturator.

In order to distinguish over the prior art there must be some functional relationship between the specific content of the printed matter to the apparatus employing the printed matter, i.e., the printed matter depends on the apparatus, and the apparatus depends on the printed matter Although factually distinct, the *In re Ngai,* 70 USPQ2d 1862 (Fed. Cir. 2004) and *In re Gulack,* 217 USPQ 410 (Fed. Cir. 1983), held the same basic premise of "where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.

In the present case Johnson discloses what is shown a printed mater in figure 1 on the handle 12 in order to provide information to the use for identifying a particular sized obturator, see col. 3, lines 53-37. The presently claimed obturator decorated with graphical and/or textual information has no functionally distinguishing relationship over Johnson in that the indicia aids one in identifying a particular sized obturator. As to claim 9, the specific indicium used to "decorate" the obturator relates to printed matter and is of no patentable significance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vidal et al (Patent no. 5,405,328). Vidal et al discloses kit in figures 15 and 16 comprising at least one obturator comprising what is considered a proximal end 202 where the obturator is grasped, a distal tip defined by any of portions 210-215 and a shaft 201 between the proximal and distal ends. Claim 18 recites the formed as a monolithic structure which s considered a product by process type of limitation of no patentable moment.[1] An orientation indicator is also recited in claim 18 as located near the proximal end, which enables a user to determine by touch the relative position of the tip at the distal end. As shown in figures 15 and 16 of Johnson handle 202 includes an abrupt disc part of larger diameter than shaft 201 adjacent the proximal end. This change in diameter manifestly serves as an orientation indicator to extent claimed where a user can determine by touch the relative position of the tip at the distal end. Hence there is no distinction between Vidal et al and the present invention to the extent claimed.

As to claim 8, members 210-215 define three obturators having blunt, tissue separating and cutting ends.

The rejection is applied in the alternative, as any differences over the claimed invention and Vidal with regard to a monolithic construction or the type of tips used are obvious. Forming the obturator as a monolithic structure is recognized to be within the level of ordinary skill as to make formally separate parts integral would have been obvious in order to obviate the need for assembly and make the use easier. As to the tips used, employing a cutting or tissue-separating tip is dependent upon the particular tools required in the specific procedure. As such these

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[1] A "product by process" claim is directed to the product per se, no matter how actually made, In re Hirao, 190 USPQ 15 at 17(footnote 3). See also In re Brown, 173 USPQ 685; In re Luck, 177 USPQ 523; In re Fessmann, 180 USPQ 324; In re Avery, 186 USPQ 161; In re Wertheim, 191 USPQ 90; and In re Marosi et al, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

parameter are considered to be of no particular criticality but a matter of design choice dependent upon the contents one desires to package in the kit.

Response to Arguments

6. Applicant's arguments filed in response to the Office Action have been fully considered but they are not persuasive. With regard to the Johnson patent applicant argues the obturator is for use in a root canal procedure while the present invention is directed to a surgical device. Is not root canal a surgical procedure? Making Johnsons' obturator a surgical device. Furthermore, the recitation of the obturator for use in endoscopic surgery is of not patentable moment. In order to further limit the claim there must be some distinction based upon the intended use recited. "However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, see M.P.E.P. § 2111.02 THE INTENDED USE MAY FURTHER LIMIT THE CLAIM IF IT DOES MORE THAN MERELY STATE PURPOSE OR INTENDED USE. The examiner can see no structural differences between the claimed invention and the prior art of Johnson based upon the intended use recited.

With regard to Johnson having indicators 20 described to determine the depth, the issue is not what the patent states within the four corners of the document, but whether Johnson is "capable of" performing the function recited in the claim. In this sense the washer 22, indicators 22, taper of the shaft 18 or mere shape of the handle 16 of Johnson can be considered an orientation indicator located near the proximal end which enables a user to determine by touch the relative position of the tip at the distal end, in as much as is claimed.

Accordingly, it is not agreed the claimed invention defines anything over the prior art.

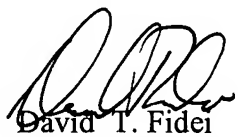
Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner concerning the merits of the claims should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

dtf
August 8, 2005